

4. (Amended) A method according to claim 2 [and/or 3, **characterised** in that] comprising the steps of subjecting clinical samples[, such as body fluids, are subjected] directly to tuberculosis diagnosis and measuring the alanine dehydrogenase activity [is measured].

a<sup>2</sup>  
cont'd

5. (Amended) A method according to claim 2, [**characterised** in that] comprising the step of differentiating at least one of cells, strains [and/or] and species of disease-causing organisms (mycobacteria) [are differentiated] from non-virulent cells and strains.

6. (Amended) A method according to claim 5, [**characterised** in that] comprising the steps of identifying and differentiating at least one of cells, strains [and/or] and species of disease-causing organisms of the *M. tuberculosis* complex [are identical and differentiated].

7. (Amended) A method according to [any one of the preceding claims, **characterised** in that the method is carried] claim 2, wherein said steps are carried out in the presence of substances that inhibit at least one of tuberculosis and other mycobacterial infections of humans and animals and [those] optionally recovering said inhibiting substances [are optionally recovered].

8. (Amended) A method according to [any one of the preceding claims, **characterised** in that it is] claim 2, wherein said steps are carried out

- (i) to control epidemics and/or
- (ii) after vaccinations (vaccination follow-up) in humans [and] or animals.

9. (Amended) A DNA sequence selected from the group consisting of the following [group or] partial sequences and other partial sequences of the alanine dehydrogenase gene of *M. tuberculosis* (Fig. 2.5):

<u>Name</u>	<u>Sequence</u>	<u>Orientation</u>
AlaDH-F1	5'-ATGCGCGTCGGTATTCCG-3'	forward
AlaDH-F1+	5'-GCGCGTCGGTATTCCGACCG-3'	forward
AlaDH-F2	5'-GAGACCAAAACAACGAA-3'	forward
AlaDH-F4	5'-GAATTCCGATCAGCAATCTTGCAGA-3'	forward
AlaDH-F5	5'-GCCCCGATCAGCGAAGTC-3'	forward
AlaDH-F6	5'-GGGGCCCTCCTGGTGCC-3'	forward
AlaDH-F7	5'-GACGTCGACCTACGCGCTGAC-3'	forward
AlaDH-R1	5'-CTCGGTGAACGGCACCCC-3'	reverse
AlaDH-R2	5'-GGCCAGCACGCTGGCGGG-3'	reverse
AlaDH-R3	5'-CACCCGTTCCGACAGTAA-3'	reverse
AlaDH-R4	5'-CGCGGCCGACATCATCGC-3'	reverse
AlaDH-R5	5'-GGCCGACATCATCGCTTCCC-3'	reverse
AlaDH-R6	5'-CGAGACTAATTGGGTGCCTTGGC-3'	reverse
AlaDH-R7	5'-ATTTGGGTGCCTTGGC-3'	reverse
AlaDH-RM	5'-GGCGGCGAGTCGACCGGC-3'	reverse

[and] partial sequences thereof and sequences that are [hybridisable] hybridizable therewith [preferably at a temperature of at least 20°C and especially at a concentration of 1M NaCl and a temperature of at least 25°C], for the diagnosis of tuberculosis and other mycobacterial infections in humans [and] or animals.

10. (Amended) [The use of a DNA sequence according to claim 9] A method for the diagnosis of tuberculosis and other mycobacterial infections in humans and animals comprising the step of using said DNA sequence of claim 9 in said diagnosis. <sup>of said set</sup>

11. (Amended) A method according to claim 10, [characterised in that a] comprising the step of using said DNA sequence [according to claim 9 is used] for at least one of

(i) [for hybridisation] hybridization,

(ii) [for] culture confirmation of isolated strains [and/or] and.

(iii) [for] chromosomal fingerprinting, and comprising the step of determining and differentiating at least one of cells, strains [and/or] and types of mycobacteria [are determined and differentiated] and/or [are used for the diagnosis of] diagnosing mycobacterial infections.

12. (Amended) A method according to claim 10 [or 11, **characterised** in that] comprising the step of differentiating at least one of cells, strains [and/or] and species of virulent mycobacteria [are differentiated] from non-virulent cells, strains and/or species.

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cont'd

13. (Amended) A method according to claim 10, [**characterised** in that cells, strains and/or species of the *M. tuberculosis* complex and other mycobacteria] comprising the steps of

(i) [are isolated] isolating cells, strains and/or species of at least one of the *M. tuberculosis* complex and other mycobacteria,

(ii) recovering crude or purified genomic DNA or RNA [is recovered], and,

(iii) identifying a fragment that is identical or virtually identical to the sequence of the alanine dehydrogenase gene of *M. tuberculosis* (Fig. 2.3) [is identified, preferably by amplification using a DNA sequence according to claim 9 as a primer sequence, after which digestion is carried out with a restriction enzyme, especially BglIII, and gel electrophoresis of the digested amplified DNA is carried out and/or the DNA sequence of the amplified DNA is determined].

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14. (Amended) A method according to claim 2 <sup>or claim 10</sup> [and/or 10, **characterised** in that] comprising the step of

diagnosing a clinical sample [is used directly and diagnosed] for tuberculosis in humans [and] or animals.

a<sup>2</sup>  
cont'd.

15. (Amended) A method according to claim 2 [and/or 10, **characterised** in that the method is] carried out in the presence of substances that inhibit tuberculosis or mycobacterial infections of humans [and] or animals and comprising the step of determining and recovering or making inhibiting substances [determined are recovered or made].

16. (Amended) A method according to claim 10[, **characterised** in that it is] used in at least one of

- (i) [in] antimycobacterial chemotherapy,
- (ii) [in] the control of epidemics [and/or] and
- (iii) after vaccinations (vaccination follow-up) in humans [and] or animals.

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Please add new claims 17 and 18 as follows:

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17. A method according to claim 3 wherein the pathogen is *M. tuberculosis*.

18. A method according to claim 4 wherein the clinical sample is a body fluid.

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